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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,388	02/23/2004	Neil C. Leatherbury	121-02	6576
23713	7590	02/22/2006	EXAMINER	
GREENLEE WINNER AND SULLIVAN P C			KIM, JOHN	
4875 PEARL EAST CIRCLE			ART UNIT	
SUITE 200			PAPER NUMBER	
BOULDER, CO 80301			3733	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/785,388	Applicant(s) LEATHERBURY ET AL.	
	Examiner John Kim	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 6,7 and 9-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8 and 24-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/22/04, 12/7/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of group I (claims 1-10 and 24-29) in the reply filed on 1/17/06 is acknowledged. The traversal is on the ground(s) that the inventions "share functional and structural features" and thus "a search of all four groups of claims does not represent an undue search burden upon the Office." This is not found persuasive because a serious burden on the examiner may be shown by prima facie if the examiner shows separate classifications for the inventions. (MPEP 808.02) In the instant case, the inventions have separate classifications, as noted in the restriction requirement of the previous office action.

The requirement is still deemed proper and is therefore made FINAL.

Furthermore, applicant elects species of group A (figures 1-3). Applicant elects claims 1-5, 8, and 24-29 read on the elected species.

Claims 6, 7, and 9-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/17/06.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 24, 26, 27, and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 18, 22, 26, 27, and 28 of copending Application No. 11/292807. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 18, 22, 26, 27, and 28 of copending Application No. 11/292807 set forth all the limitations of claims 1, 4, 24, 26, 27, and 29 in the immediate application, such as a tubular outer shaft, inner shaft with a cannula in the middle, different sizes of shafts and bores, and the methods steps.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, and 26-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 17-19 of copending Application No. 11/290142. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, and 17-19 of copending Application No. 11/290142 set forth all the limitations of claims 1, and 26-29

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in the immediate application, such as a tubular outer shaft, inner shaft, a cutting device, different sizes shafts and bores, and an implant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cannulated inner shaft (claim 4) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24 and 25 recites the limitation "said loading device" in line 4 and 5.

There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 5, 26, 27, and 29 rejected under 35 U.S.C. 102(b) as being anticipated by Torrie et al (US Pat 6358253).

Regarding claims 1 and 26, Torrie discloses the invention with a tubular outer shaft (12, figure 2a, col 4:39-67) with proximal and distal ends, a longitudinal axis and

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an internal bore (19), and an inner shaft (50, figure 2f, col 6:30-7:9) having distal and proximal ends and slides inside outer shaft. Regarding claims 2 and 29, examiner notes the applicant does not invoke 35 USC 112 6th paragraph since applicant fails the 3-prong analysis (claim 2). Torrie discloses of having multiple shafts provided for each size graft. (col 4:60-67) Regarding claim 3 and 27, Torrie discloses of having an implant (87) that is initially inserted into the proximal end of the outer shaft and then is moved to the distal end. (col 8:51-9:3) Regarding claim 5, Torrie discloses of having a slot in the distal end of the outer shaft (col 5:9-13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Torrie et al (US Pat 6358253).

Torrie discloses the claimed invention with a button of plastic or soft material to prevent damage to the implant during insertion. Torrie fails to disclose having a smooth-rounded surface on the proximal and distal ends of the outer and inner shafts. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the proximal and distal ends of the outer and inner shafts with smooth rounded surfaces, since applicant has not disclosed that such

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solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of not damaging the implant and surrounding tissues. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Torrie et al (US Pat 6358253) in view of Burkhart (US Pat 5993451).

Torrie discloses the claimed invention except for having the inner shaft cannulated. Burkhart discloses of having an inner shaft (2, 4) with a cannula (8) in the center (col 3:19-26). This allows the surgeon to thread a suture, attached to a suture anchor, through the cannula. (col 2:4-11, abstract). Thus it would have been obvious to one skill in the art at the time the invention was made to construct the implant delivery device with the cannulated inner shaft in view of Burkhart, in order to have a suture threaded through the cannula of the inner shaft, thus making one less step for the surgeon to perform the surgery.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Torrie et al (US Pat 6358253) in view of Reynolds (US Pat 5888061).

Torrie discloses the claimed invention and the cutting of the implant. Torrie fails to disclose of using a knife. Reynolds discloses a knife that cuts the end of cylindrical objects, like a cigar or an implant (figure 5). This would allow a surgeon to cut the implant, flush with the surrounding tissue. It would have been obvious to one skill in the

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art at the time the invention was made to construct the implant delivery device with the knife in view of Burkhart, in order to have the implant cut so that the implant was flush with the surrounding tissue.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-2817. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JK (2)


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER